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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/552,649

12/04/2006

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EXAMINER

JUNG, UNSU

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

06/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/552,649 | Applicant(s) GRANELI ET AL. | |
| | Examiner UNSU JUNG | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 9-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Examiner for the current application has been changed from Dennis Heyer to Unsu Jung in Art Unit 1641. Any inquiry concerning this application should be directed to Unsu Jung, whose contact information is provided in the conclusion section of this Office Action.

Election/Restrictions

2. Applicant's election with traverse of Group I (claims 1-10) and election of species (1) the vesicles are not coated with an outer shell, (2) the vesicles do not comprise a disclosed compound, and (3) the structure is not adapted to be released in the reply filed on April 13, 2009 is acknowledged. The traversal is on the ground(s) that there would not be undue burden for the Examiner to examine all the claims owing to overlapping fields of search. This is not found persuasive because the inventions of Groups I-IX are distinct for the reasons given in the Office Action dated February 4, 2004. Furthermore, because the search required for Group I is not required for Groups II-IX, restriction for examination purposes as indicated is proper. Literature search for each method and apparatus is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

Claims 1-5 and 8 read on the elected species as acknowledged by the applicant in the reply filed on April 13, 2009.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

3. Claims 1-62 are pending, claims 6, 7, and 9-62 have been withdrawn from consideration, and claims 1-5 and 8 are currently under consideration for patentability under 37 CFR 1.104.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The instant application is a national phase under 35 U.S.C. 371 of PCT International Application No. PCT/SE2004/000555, filed on April 7, 2004 and claims priority under 35 U.S.C. §119 to Application Serial No. 60/461,197 filed April 9, 2003.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Sweden 0301038-6 filed on April 7, 2003 in the instant application.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on August 18, 2006 has been considered by the examiner.

Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration dated August 18, 2006. See 37 CFR 1.52(c).

Specification

7. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The current Abstract uses the legal phraseology "said" in lines 1, 2, and 5. Such legal phraseology often used in patent claims, such as "means" and "said," should be avoided in the Abstract.

Claim Objections

8. In claims 1, 2, and 5, the use of the term “vesicle attached linkers” is not consistent as the same term with or without hyphen is used interchangeably. Applicant is advised to use a consistent term for vesicle attached linkers, either with or without the hyphen.

9. Claim 5 is objected to because of the following informalities: the term "said linker" in lines 3 and 4 should be corrected to “vesicle-attached linkers” in order to clearly provide antecedent basis for the term "said linker" in lines 3 and 4 of claim 5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In claim 2, the terms “each linker” in line 3 and “said linker” in line 4 are vague and indefinite. There are two types of linkers (surface-immobilized linkers and vesicle-attached linkers) recited in claim 1, from which claim 2 depends.

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Therefore, it is unclear to which linker the terms “each linker” in line 3 and “said linker” in line 4 of claim 2 are referring. For the purpose of examination, the terms “each linker” in line 3 and “said linker” in line 4 have been interpreted as referring to surface-immobilized linkers.

b. Claim 8 recites the limitations "said hybridisation" and “said oligonucleotides” in line 2. There is insufficient antecedent basis for this limitation in the claim. Change of dependency from claim 1 to claim 4 would obviate this rejection.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-5 and 8 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Bredehorst et al. (WO 02/081739 A2, published Oct. 17, 2002 and filed Apr. 9, 2001) (hereinafter “Bredehorst”).

Bredehorst anticipates instant claims by teaching a biologically functional surface immobilized multilayer structure comprising a plurality of vesicles (affinity liposomes) sufficiently spaced apart from the surface (see entire document, particularly p5, lines 17-27 and Fig.'s 1-4). The vesicles are directly attached to the structure by surface-immobilized linkers (analyte and/or capture oligonucleotides) with vesicle-attached linkers (affinity components) and optionally by vesicle-attached linkers to another vesicle (Fig. 4). The vesicles comprise the biologically active compounds (p5, lines 17-27), which provide the structure with its biological functionality.

With respect to claim 2, Bredehorst teaches that the vesicles are directly attached to the surface immobilized linkers with vesicle-attached linkers so that at least two vesicles are attaché to each surface immobilized linker (Fig. 4). The vesicle attached linker is adapted to bind to the surface immobilized linker but not to another vesicle attached linker (Fig. 4).

With respect to claim 3, Bredehorst teaches that the vesicles are attached to the structure by a) the surface immobilized linker and b) vesicle-attached linkers, so as to provide said structure with two or more of vesicle layers (Fig. 4).

With respect to claims 4 and 8, Bredehorst teaches that the linkers comprise oligonucleotides, and the binding of a linker to another linker is mediated through hybridization of the oligonucleotides (p8, lines 12-33), which is essentially sequence specific.

With respect to claim 5, Bredehorst teaches that the vesicle attached linkers are attached to the vesicles via a covalent bond to the vesicle via a functionalized group comprised in said linker (p10, line 30-p11, line 10).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-5 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/590,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because each recites a biologically functional surface immobilized multilayer structure comprising a plurality of vesicles

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sufficiently spaced apart from the surface. The vesicles are directly attached to the structure by surface-immobilized linkers with vesicle-attached linkers and optionally by vesicle-attached linkers to another vesicle. The vesicles comprise the biologically active compounds, which provide the structure with its biological functionality. Therefore, the claims of the copending Application anticipate the claims of instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Prior Art of Record

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following prior art references have been cited in the International Search Report for PCT/SE2004/000555.

- Bredehorst et al. (WO 02/081738 A2, Oct. 17, 2002) teaches the use of liposomes containing encapsulated reporter molecules as detector units (see entire document).
- Bredehorst et al. (WO 02/082078 A2, Oct. 17, 2002) teaches the use of liposomes containing encapsulated reporter molecules as detector units (see entire document).
- Patolsky et al. (*J. Am. Chem. Soc.*, 2000, Vol. 122, pp418-419) teaches amplified microgravimetric quartz-crystal-microbalance assay of DNA using oligonucleotide-functionalized liposomes or biotinylated liposomes (see entire document).

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- Patolsky et al. (*J. Am. Chem. Soc.*, 2001, Vol. 123, pp5194-5205) teaches electronic transduction of DNA sensing processes on surfaces using amplification of DNA detection by tagged liposomes (see entire document).

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/
Unsu Jung
Primary Examiner
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